**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| In Re Genta, Inc., | : | |
| Securities Litigation, | : | Civil Action No. 04-2123 (JAG) |
| | : | **OPINION** |
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**GREENAWAY, JR., U.S.D.J.**

This matter comes before the Court on the Motion to Dismiss of Defendants Genta, Inc. and Raymond P. Warrell, Jr. (collectively, "Defendants"). Defendants have filed a Motion to Dismiss the Amended and Consolidated Complaint, pursuant to FED. R. CIV. P. 12(b)(6) and 9(b), and the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4. For the reasons set forth below, the Motion to Dismiss will be granted in part and denied in part.

## INTRODUCTION

Defendant Genta, Inc. ("Genta" or the "Company") is a Delaware corporation in the pharmaceutical industry; it has been working at developing and commercializing new drugs for cancer and related diseases. Genta is a publicly traded company on NASDAQ with the symbol GNTA. The company's lead investigational drug during the relevant time period was named Genasense, also known as oblimersen sodium. Defendant Raymond P. Warrell, Jr. ("Warrell") served as Chairman, President, and Chief Executive Officer ("CEO") of Genta.

Lead Plaintiffs Bal Harbor Financial LLC, William Nasser, Jr., David Smith, Brian R. Nickerson, and Ralph LeMar (collectively, "Plaintiffs") filed a securities class action complaint

against Genta and Warrell alleging (1) violations of § 10(b) of the Exchange Act and Rule 10b-5 by all defendants (fraud claim) and (2) violations of § 20(a) of the Exchange Act by Warrell (control person claim). Plaintiffs brought a class action on behalf of a class consisting of all persons other than Defendants who purchased Genta securities or sold Genta put options during the class period of December 14, 2000 and May 3, 2004, inclusive (the "Class Period"). Specifically, Plaintiffs allege that Defendants made materially false and misleading statements relating to the development of Genasense during the Class Period, artificially inflating the market price of Genta securities, that Plaintiffs relied on these false statements and acquired Genta securities during the Class Period, and that Plaintiffs were thereby damaged.

Defendants have moved to dismiss the Complaint, arguing that it (1) fails to allege any material misstatement or omission, (2) fails to allege sufficient facts to satisfy the pleading particularity requirements of the PSLRA and FED. R. CIV. P. 9(b), (3) fails to plead a scheme or artifice to defraud under Rule 10b-5(a) and (c), and (4) fails to support a claim of control person liability under § 20(a) of the Exchange Act, since it fails to plead a predicate violation of § 10(b).

Plaintiffs allege that, during the Class Period, Genasense was Genta's lead investigational drug, and Genta sought to obtain FDA approval for its manufacture and sale. In March of 2000, Genta began Phase 3 clinical trials of Genasense for the treatment of cancer. Clinical trials were conducted for use of the drug with three types of cancer: malignant melanoma, chronic lymphocytic leukemia, and myeloma. This action concerns statements made in regard to the Phase 3 clinical trial for the treatment of malignant melanoma. In this clinical trial, the effect of treatment with Genasense in combination with dacarbazine was compared to treatment with dacarbazine alone. The aim of the clinical trials was to obtain data to be included in a new drug

application ("NDA") to the Food and Drug Administration ("FDA"). Genta filed its NDA for Genasense, seeking approval for the treatment of malignant melanoma, in December of 2003.

On April 30, 2004, the FDA posted on its website summaries showing negative assessments of the research data from the Genasense clinical trial. On April 30, 2004, Genta common stock closed at $8.60 per share, down 40% from the previous day's closing price of $14.43. On May 3, 2004, after reviewing the melanoma Phase 3 clinical test data submitted with the NDA, the Oncology Drug Advisory Committee ("ODAC") to the FDA voted 13-3 to reject the approval of Genasense for the treatment of melanoma in conjunction with standard therapy. Genta subsequently withdrew the NDA.

Plaintiffs allege that Defendants made materially false statements in three areas. First, Genta stated that the clinical trials were well-designed, when they were in fact defective in design. Second, they mischaracterized the results from the Phase 3 melanoma clinical test, depicting them as more positive than they in fact were. Third, they made false and misleading statements as to when the results of the melanoma clinical trial would be available.

Plaintiffs attribute substantial harm and loss to the class due to Defendants' materially false and misleading information. Plaintiffs allege that Defendant's investors, in the aggregate, suffered substantial losses as the price of Genta common stock declined by over 92% from a class period high closing price of $18.25 per share on March 21, 2002, to close at $1.38 per share on August 13, 2004.

## ANALYSIS

### I. Governing Legal Standards

A. Standard for a Rule 12(b)(6) Motion to Dismiss

On a motion to dismiss for failure to state a claim, pursuant to FED. R. CIV. P. 12(b)(6), the court must accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the non-moving party. See Oshiver v. Levin, Fishbein, Sedran & Berman, 38 F.3d 1380, 1384 (3d Cir. 1994). A complaint should be dismissed only if the alleged facts, taken as true, fail to state a claim. See In re Warfarin Sodium, 214 F.3d 395, 397 (3d Cir. 2000). The question is whether the claimant can prove any set of facts consistent with his or her allegations that will entitle him or her to relief, not whether that person will ultimately prevail. See Hishon v. King & Spalding, 467 U.S. 69, 73 (1984). While a court will accept well-pled allegations as true for the purposes of the motion, it will not accept unsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegations. See Sutton v. United Airlines, Inc., 527 U.S. 471, 475 (1999). All reasonable inferences, however, must be drawn in the plaintiff's favor. See Sturm v. Clark, 835 F.2d 1009, 1011 (3d Cir. 1987). Moreover, the claimant must set forth sufficient information to outline the elements of his or her claims or to permit inferences to be drawn that the elements exist. See FED. R. CIV. P. 8(a)(2); Conley v. Gibson, 355 U.S. 41, 45-46 (1957). "The defendant bears the burden of showing that no claim has been presented." Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005).

B. Rule 9(b)

In pleading fraud, FED. R. CIV. P. 9(b) establishes a heightened pleading standard,

requiring "plaintiffs to plead 'the who, what, when, where, and how: the first paragraph of any newspaper story.'" In re Advanta Corp. Sec. Litig., 180 F.3d 525, 534 (3d Cir. 1999) (quoting DiLeo v. E&Y, 901 F.2d 624, 627 (7th Cir. 1990)). "Although Rule 9(b) falls short of requiring every material detail of the fraud such as date, location, and time, plaintiffs must use 'alternative means of injecting precision and some measure of substantiation into their allegations of fraud.'" In re Rockefeller Center Properties, Inc. Sec. Litig., 311 F.3d 198, 216 (3d Cir. 2002) (quoting In re Nice Systems, 135 F. Supp. 2d 551, 577 (D.N.J. 2001)).

C. § 10(b) of the Securities Exchange Act of 1934

Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), prohibits the use of fraudulent schemes or devices in connection with the purchase or sale of securities. Under § 10(b), it is unlawful "[t]o use or employ, in connection with the purchase or sale of any security . . . , any manipulative or deceptive device or contrivance in contravention" of any rule promulgated by the SEC designed to protect the investing public. To implement the statute, the SEC enacted Rule 10b-5, violation of which gives rise to a private cause of action. Ernst & Ernst v. Hochfelder, 425 U.S. 185 (1976); Blue Chip Stamps v. Manor Drug Stores, 421 U.S. 723 (1975). That rule, in turn, deems it unlawful

> (a) [t]o employ any device, scheme, or artifice to defraud,
>
> (b) [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) [t]o engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person in connection with the purchase or sale of any security.

17 C.F.R. § 240.l0b-5. The Supreme Court has held that standing to bring a private cause of

action under Rule l0b-5 is limited to actual purchasers or sellers of securities. Blue Chip Stamps, 421 U.S. at 749.

To state a claim for violation of Rule 10b-5, a plaintiff must allege "(1) that the defendant made a misrepresentation or omission of (2) a material (3) fact; (4) that the defendant acted with knowledge or recklessness and (5) that the plaintiff reasonably relied on the misrepresentation or omission and (6) consequently suffered damage." In re Westinghouse Sec. Litig., 90 F.3d 696, 710 (3d Cir. 1996). Rule 9(b) imposes heightened pleading requirements on plaintiffs in Rule 10b-5 actions. "In order to state a viable claim pursuant to Rule 10b-5, 'Rule 9(b) requires a plaintiff to plead (1) a specific false representation [or omission] of material fact; (2) knowledge by the person who made it of its falsity; (3) ignorance of its falsity by the person to whom it was made; (4) the intention that it should be acted upon; and (5) that the plaintiff acted upon it to his damage.'" Rockefeller Center Properties, 311 F.3d at 216 (internal citations omitted).

The PSLRA, 15 U.S.C. § 78u-4, further refines this standard by requiring that a complaint which asserts a §10(b) claim "shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). Further, if "proof that the defendant acted with a particular state of mind" is a required element of the claim, "the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2).

The Third Circuit has articulated the analysis for the scienter pleading requirements of the

PSLRA. A plaintiff who alleges securities fraud must "allege specific facts that give rise to a 'strong inference' that the defendant possessed the requisite intent." In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1418 (3d Cir. 1997). A plaintiff may establish this strong inference of scienter "'either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness.'" Burlington, 114 F.3d at 1418 (quoting Acito v. IMCERA Group, Inc., 47 F.3d 47, 52 (2d Cir. 1995)). Recklessness, in turn, involves "'not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.'" In re Advanta Corp., 180 F.3d at 535 (quoting McLean v. Alexander, 599 F.2d 1190, 1197 (3d Cir. 1979)). "[S]cienter may be alleged by stating with particularity facts giving rise to a strong inference of conscious wrongdoing, such as intentional fraud or other deliberate illegal behavior." Id.

Accordingly, "unless plaintiffs in securities fraud actions allege facts supporting their contentions of fraud with the requisite particularity mandated by Rule 9(b) and the Reform Act [PSLRA], they may not benefit from inferences flowing from vague or unspecific allegations — inferences that may arguably have been justified under a traditional Rule 12(b)(6) analysis." In re Rockefeller, 311 F.3d at 224. "In other words, pursuant to this 'modified' Rule 12(b)(6) analysis, 'catch-all' or 'blanket' assertions that do not comply with the particularity requirements are disregarded." Cal. Pub. Employees. Ret. Sys. v. Chubb Corp., 394 F.3d 126, 144 (3d Cir. 2004).

## II. Defendants' 12(b)(6) Motion to Dismiss

A. Claim for Violation of Exchange Act § 10(b) and Rule 10b-5(b) Against Genta

Plaintiffs have stated a valid claim for relief under Exchange Act § 10(b) and Rule 10b-5(b) against Genta relating to statements about Genasense side effects. On March 12, 2004, Genta filed a form 10-K with the SEC for 2003 signed by Warrell, among others. (Compl. ¶ 77.) Regarding the results of the Phase 3 malignant melanoma clinical trial, the 10-K stated, "[t]he addition of Genasense to dacarbazine did not appear to be associated with serious, previously unreported adverse reactions compared with the use of dacarbazine alone." Id. On February 12, 2004, Genta issued a press release which stated, "Genta completed the Genasense NDA submission for advanced melanoma in December." (Compl. ¶ 75.) On April 30, 2004, Genta issued a press release stating that the FDA had posted on its web site certain briefing documents. (Compl. ¶ 79.) Plaintiffs allege that the FDA posted a summary which stated:

> (d) 'the combination [Genasense] arm was associated with increased toxicity and discontinuations due to adverse events (AEs) including 69 (18.6%) patients who discontinued therapy for adverse events on the G3139 [Genasense] arm versus 39 (10.8%) on the DTIC [dacarbazine] alone arm'and 'the rate of serious adverse events (SAEs) was 40% on the G3139 [Genasense] arm versus 27% on DTIC alone.'

Id.

Accepting the allegations above as true, one may reasonably infer that, at the time Genta filed its 10-K statement, it had already submitted an NDA containing data evidencing the false or misleading nature of the 10-K statement about side effects. It may be reasonably inferred that the March 12, 2004 10-K statement was false or misleading, and known by Genta to be false or misleading, when made. This constitutes circumstantial evidence of either reckless or conscious

misbehavior. The 10-K statement implies that clinical trial results did not associate an increased rate of serious adverse events due to treatment with Genasense; this implication is contrary to the data submitted to the FDA in the NDA. The danger of misleading investors with this 10-K statement is clear and unequivocal. This Court is certainly led to believe that the management of Genta must have been aware of it. The facts alleged give rise to a strong inference that Genta management acted with the required state of mind.

On April 30, 2004, Genta common stock closed at $8.60 per share, down 40% from the previous day's closing price of $14.43. (Compl. ¶ 80.)

It may be reasonably inferred that the statement about side effects was material. First, Defendants have not argued that this is not material information. Moreover, proving materiality entails "a showing of a substantial likelihood that, under all the circumstances, the omitted fact would have assumed actual significance in the deliberations of the reasonable shareholder." TSC Indus. v. Northway, Inc., 426 U.S. 438, 449 (1976). Given the allegation that the side effect differential was significant enough that the FDA listed it in a summary of issues in anticipation of the ODAC meeting on the approval of Genasense, a reasonable inference may be drawn in Plaintiffs' favor that the side effects differential would have been significant information in the purchasing/selling deliberations of the reasonable shareholder.

Accepting the allegations as true, plaintiffs reasonably relied on the statements and suffered damage when the stock price fell on April 30, 2004, after the FDA posted statements about Genta's side effects data on its website.

Viewing these allegations in the light most favorable to the non-moving party, and making all reasonable inferences in the plaintiffs' favor, plaintiffs have alleged every element of a cause

of action under § 10(b) and Rule 10(b)-5: the 10-K statement made a misrepresentation of a material fact, with knowledge or recklessness, which Plaintiffs relied upon, and consequently suffered damage.

Moreover, plaintiffs have alleged facts supporting their contentions of fraud with the requisite particularity mandated by Rule 9(b) and the PSLRA. Plaintiffs have alleged exactly what misleading statements were made, and reasons why these statements were misleading, thus satisfying the requirements of 15 U.S.C. § 78u-4(b)(1). Plaintiffs have also pled with particularity specific facts which, if true, constitute strong circumstantial evidence of conscious misbehavior, satisfying the requirements of 15 U.S.C. § 78u-4(b)(2) under the Burlington standard. The Motion to Dismiss this claim should be denied.

Plaintiffs' Complaint alleges that Genta made other materially false and misleading statements, which may state a claim for relief under § 10(b) of the Exchange Act and Rule 10b-5. Because this Court finds that Plaintiffs have pled sufficient facts regarding the 10-K statement to state a claim for relief under their first cause of action against Genta, it need not address the sufficiency of the remaining allegations.

B. Claim for Violation of Exchange Act § 10(b) and Rule 10b-5(b) Against Warrell

Defendants argue that Plaintiffs fail to meet the heightened pleading requirements of the PSLRA with regard to the element of scienter in their first cause of action against Warrell. Defendants cite In re Advanta, 180 F.3d at 539, for the proposition that one cannot infer scienter from the mere fact of a person's high position within a company. As such, Defendants argue, Plaintiffs have failed to state with particularity facts giving rise to a strong inference that Warrell acted with the required state of mind, as required by 15 U.S.C. § 78u-4(b)(2).

Indeed, Plaintiffs have not alleged with particularity facts which, if true, would prove that Warrell had the requisite state of mind when he signed the 10-K, with regard to the statement about side effects. They have, however, alleged with particularity facts sufficient to draw a reasonable inference in their favor that there is strong circumstantial evidence of Warrell's conscious misbehavior or recklessness.

Comprehensive knowledge of the clinical trials involved in the development of Genta's lead pharmaceutical product may be reasonably imputed to Warrell, who was President, Chairman, and CEO of the company. District courts in this circuit and others have found this to be a reasonable inference in similar cases. See, e.g., In re Vicuron Pharms., Inc. Sec. Litig., 2005 U.S. Dist. LEXIS 15613, *28 (E.D.Pa. 2005) (the importance to the company of the lead drug under development warranted an inference of recklessness, at the least, of its officers and directors as to misstatements related to Phase 3 clinical trials of the drug); In re Viropharma, Inc., Sec. Litig., 2003 U.S. Dist. LEXIS 5623, *31 (E.D.Pa. 2003) (because drug under development was company's leading product, it can be assumed that Chairman and CEO knew results of Phase 2 clinical trials). See also In re Regeneron Pharms., Inc. Sec. Litig., 2005 U.S. Dist. LEXIS 1350, *69 (S.D.N.Y. 2005) (because drug under development was a "make or break" product for the drug company, this supported inferences of scienter under PSLRA of chairman and CEO of negative information from clinical trials); In re NeoPharm, Inc., 2003 U.S. Dist. LEXIS 1862, *35 (N.D.Ill. 2003) (plaintiff pled sufficient facts to infer that chairman and CEO of drug company knew of results of Phase 2 clinical trials).

Defendants quote Advanta for the principle that high position alone within a company cannot justify an inference of scienter, overlooking that Plaintiffs here do not argue that Warrell

must have known only because he was President and CEO, but rather, that Warrell must have known about the clinical trials because 1) he was "personally involved in the design" of the trials (Compl. ¶ 32); 2) he was President and CEO of the company; and 3) the trials were crucial to the success of the company's lead product. Here, Genta's success likely hinged to a great degree on the results of its clinical trials, whereas, in Advanta, the repricing of credit card teaser rates was of minor significance to the defendant officers and directors, and it was not alleged that defendants had involvement in the design of the program. Advanta is thus distinguishable and not contrary authority.

The analysis of the remaining elements of a claim under Rule 10(b)-5 is the same as that presented above for Genta. Plaintiffs have sufficiently pled all elements of a claim for relief against Warrell under Exchange Act § 10(b) and Rule 10b-5(b). The Motion to Dismiss this claim should be denied.

C. Claim for Violation of Exchange Act § 10(b) and Rule 10b-5(a) and (c)

Defendants argue that Plaintiffs' Complaint pleads causes of action under Rule 10b-5(b) only, and that the Complaint does not support any claim for a plan or scheme under Rule 10b-5(a) or 10b-5(c): "Plaintiffs are precluded from asserting that this case is anything but a Rule 10b-5(b) case." (Def.'s Mem. of Law 42.) In their reply, Plaintiffs did not disagree. Yet, the reach of Rule 10b-5(c) is very broad: that provision makes it unlawful to "engage in any act . . . which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b-5(c). If the Complaint supports a claim for making an untrue statement, and also supports an inference of scienter for fraud, under Rule 10b-5(b), it must logically support a claim for an act to defraud under Rule 10b-5(c): making an untrue statement

with scienter for fraud is an act to defraud.

Rule 10b-5(a) does not define a scheme, nor have courts delineated a clear meaning. See In re Homestore.com, Inc. Sec. Litig., 252 F. Supp. 2d 1018, 1039 (C.D.Cal. 2003) ("What defines a 'scheme to defraud' is elusive and not well-examined in the case law"). Yet this Court need not explicate its meaning here, due to the interaction of FED. R. CIV. P. 9(b), the PSLRA, and Rule 10b-5(a). Because 10b-5(a) covers schemes "to defraud," this invokes the state of mind requirements of Rule 9(b) and the PSLRA. See 15 U.S.C. § 78u-4. Thus, to withstand a motion to dismiss a claim for a scheme under Rule 10b-5(a), Plaintiffs must state with particularity facts giving rise to a strong inference that defendants acted with the required state of mind. Plaintiffs have not done so. No matter how one might reasonably define a scheme under Rule 10b-5(a), the Complaint does not speak of any scheme in the explication of the facts of the case and subsequent argument. It is not until the end, in the statement of the first claim, that reference to a scheme appears. Because Plaintiffs have not stated facts supporting an inference of the requisite state of mind to engage in a scheme to defraud, any cause of action for a scheme under Rule 10b-5(a) does not meet the heightened pleading requirements of the PSLRA.[1] This is precisely the kind of 'catch-all' assertion that the Third Circuit has held that the PSLRA bars. See California, 394 F.3d at 145. To the extent that the Complaint fails to plead a cause of action for a scheme to defraud under Rule 10b-5(a), the Motion to Dismiss should be granted.

D. Claim for Violation of Exchange Act § 20(a) Against Warrell

Defendants argue that Plaintiffs' control person cause of action against Warrell must be

[1]Rule 10b-5(a) covers "any device, scheme, or artifice to defraud." 17 C.F.R. § 240.10b-5(a). This Court makes no determination of whether Plaintiffs have stated a claim for relief for a device or artifice to defraud.

dismissed because such claims require an underlying violation of the Exchange Act, which Defendants have failed to allege sufficiently. This Court finds that Plaintiffs have stated a valid claim for relief under Exchange Act § 10(b), as well as a valid derivative claim under § 20(a). Plaintiffs have alleged as well that Warrell acted as a control person of Genta, thus stating a claim for relief under § 20(a). (Compl. ¶ 106.) The Motion to Dismiss the second claim should be denied.

## CONCLUSION

For the reasons stated above, Defendants' Motion to Dismiss the Amended and Consolidated Class Action Complaint is granted in part and denied in part. To the extent that Plaintiffs have failed to state a claim for a scheme to defraud under Rule 10b-5(a), that part of their Complaint is dismissed. As to the remainder of the Complaint, the Motion to Dismiss is denied.

S/Joseph A. Greenaway, Jr.
JOSEPH A. GREENAWAY, JR., U.S.D.J.

Dated: September 29, 2005